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7590 01/06/2010 LEYDIG, VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 N. STETSON			EXAMINER	
			SZMAL, BRIAN SCOTT	
CHICAGO, IL			ART UNIT	PAPER NUMBER
			3736	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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	Application No.	Applicant(s)				
Office Action Comments	10/790,618	VAN DER STEEN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Brian Szmal	3736				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>08 Sectors</u>	entember 2009					
<i>,</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
·	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
closed in accordance with the practice under Ex parte Quayre, 1000 O.D. 11, 400 O.G. 210.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-8 and 10-26</u> is/are pending in the a	4)⊠ Claim(s) <u>1-8 and 10-26</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-8 and 10-26</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	· · <u> </u>					
Application Papers						
9) The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on <u>01 March 2004</u> is/are: a) ☑ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)⊠ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	te				

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Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Objections

2. Claim 26 is objected to because of the following informalities: the claim discloses "The apparatus of claim 1". Claim 1 is a method claim, and therefore the phrase should read as "The apparatus of Claim 13". Appropriate correction is required.

35 USC § 112, 6th Paragraph

- 3. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:
 - An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.
- 4. Claim element "correlation detection means" in Claim 14 is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The current specification

fails to explicitly disclose if the claimed "correlation detection means" constitutes a software or hardware application.

Applicant is required to:

- (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or
- (c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.
- 5. Claim element "first activating means" in Claim 18, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The current specification fails to explicitly disclose if the "first activating means" constitutes a software application or a hardware application.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

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(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

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- (c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.
- 6. Claim element "second activating means" in Claim 19, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The current specification fails to explicitly disclose if the "first activating means" constitutes a software application or a hardware application.

Applicant is required to:

- (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or
- (c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

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Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 8. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 14 discloses a "correlation detection means". The current specification however fails to disclose the structure of the "correlation detection means".
- 9. Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In Claim 18, the claimed "first activating means" is not clearly disclosed in the current specification with respect to the "first activating means" being either a software application or a hardware application. In Claim 19, the claimed "second activating means" is not clearly disclosed in the current specification with respect to the "first activating means" being either a software application or a hardware application.

 Furthermore, with respect to the use of "first" and "second" activating means, the current specification fails to disclose more than one activating means. The use of "first"

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implies more than one, while "second" implies the use of a first activating means. As discussed in the current specification, the single activating means can be one of two different embodiments.

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- 10. Claims 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 25 and 26 disclose "wherein an optimum overlap is determined by means of a probability function representing similarity between consecutive signals".

 The current specification fails to disclose what probability function is being utilized to determine the optimum overlap. The current specification appears to imply every known probability function can be used to perform the task of determining the optimum overlap. The current specification also fails to disclose what signals are being used to determine the optimum overlap, and how the optimum overlap is being used to determine hardness information of tissue.
- 11. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 12. Claims 14, 18, 19, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 14 discloses a "correlation detection means". It is unclear to the Examiner if the claimed "correlation detection means" constitutes a software or hardware application.

Claims 18 and 19 disclose the "first activating means" and "second activating means". It is unclear to the Examiner if the claimed "first activating means" and "second activating means" constitute a software or hardware application.

Claims 25 and 26 disclose the determination of an optimum overlap. In the context of the claims, in combination with their respective independent claims, it is unclear to the Examiner what the optimum overlap has to do with the method steps of generating tissue hardness information, and the apparatus elements for generating tissue hardness information. It is also unclear how the optimum overlap is being used to generate tissue hardness information.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claims 1-8 and 10-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 fails to meet the requirement of In re Bilski, 88 USPQ2d 1385 (Fed. Cir. 2008). In re Bilksi requires the process be tied to a particular structure or perform a physical transformation of the acquired data. The steps of the identification of the strain of the tissue and relating the

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strain has no tie to a particular structure, and can also be performed by a person. The claimed steps also do not provide a physical transformation of the acquired data.

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Claims 13, 14, 18, 19 and 22 are rejected under 35 U.S.C. 101 because the 15. claimed invention is directed to non-statutory subject matter. Claim 13 discloses a "sensor movable through a blood vessel or body cavity". The current language renders the claim non-statutory. The language should be amended to read as a "sensor adapted to be moved through a blood vessel or body cavity" to be statutory. Claim 14 discloses a "correlation detection means", but the current specification fails to disclose the structure constituting the "correlation detection means". Since the "correlation detection means" can be interpreted as a software application, the claimed "correlation detection means" lacks any sufficient structure and therefore is nonstatutory. Claims 18 and 19 disclose a "first activating means" and "second activating means", but the current specification fails to explicitly disclose the structure performing the activation, and therefore can be interpreted as a software application. Since the "first activating means" and "second activating means" can be interpreted as a software application, the claimed "first activating means" and "second activating means" lack any sufficient structure and therefore is nonstatutory. Regarding Claim 22, the claim is rendered non-statutory due to "which can be inserted into a blood vessel". A device that is placed on or inserted into a body should be "adapted to be placed" into the body or onto the body to be statutory.

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16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 17. Claims 1-4, 6-8, 11, 13, 14, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) in view of Porat et al (2003/0220556 A1).

Torp et al disclose a means for real-time calculation and display of strain in ultrasound imaging and further disclose receiving signals from a tissue with a sensor for measuring the deformation of the tissue in a measuring plane defined by the sensor; the sensor is placed in a direction transverse to the measuring plane while being subject to a varying pressure (the catheter has ultrasound sensors oriented transversely to the longitudinal axis of the catheter, thus any movement in a vessel would have a movement being transverse to the measuring plane); a varying pressure exerted on the tissue; identifying strain of the tissue from the signals received by the sensor; relating the strain to at least one of either hardness or elasticity; correlating signals acquired consecutively over time, where the signals are representative of the deformation of the tissue at positions of the sensor moved with respect to other positions of the sensor; calculating by means of the correlating step, strain in a tissue surface or tissue volume part; displaying elasticity or hardness parameters of a tissue surface or tissue volume part; the signals are echographic data detected with an acoustic sensor; displaying elasticity or hardness parameters of the tissue with position information of the sensor or

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tissue; signals possessing an overlap are received; a processor for collecting and processing signals from the sensor to identify strain of the tissue and to relate strain to elasticity or hardness parameters of a tissue surface or tissue volume part; a first activating means for activating data storage; and the activating means are connected with the correlation detection means to become active at a predetermined correlation. See Column 5, lines 11-34; Column 6, lines 14-17; Column 7, lines 54-61; Column 8, lines 8-17 and 53-67; and Column 9, lines 1-9.

Torp et al however fail to disclose moving the sensor along the tissue in a direction transverse to the measuring plane and while the tissue is subject to a varying pressure; the signals are received during practically continuous motion of the sensor; the signals come from a blood vessel wall and the data is received only during a specific time period; the sensor is movable through the blood vessel or body cavity for recording signals from tissue while being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor; and the sensor is arranged in a catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pull back of the catheter.

Porat et al disclose a means for tissue characterization and further disclose moving the sensor along the tissue in a direction transverse to the measuring plane; the signals are received during practically continuous motion of the sensor; the signals come from a blood vessel wall and the data is received only during a specific time period; the sensor is movable through the blood vessel or body cavity for recording signals from tissue while being controllably moved along the tissue in a direction

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transverse to a measuring plane defined by the sensor; and the sensor is arranged in a catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pull back of the catheter. See Paragraphs 0286 and 0298.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Torp et al to include the ability to move the sensor along a blood vessel, as per the teachings of Porat et al, since it would provide a means of determining a tissue parameter along a length of tissue.

18. Claims 5, 10, 12, 15-17, 19, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) in view of Porat et al (2003/0220556 A1) as applied to claims 1 and 13 above, and further in view of Panescu et al (5,848,969).

Torp et al and Porat et al, as discussed above, disclose a means for measuring a tissue parameter along a length of a blood vessel but fail to disclose the signals are optical data detected with an optical sensor; the signals at as assumed cyclic pressure change are received at predetermined time intervals in a pressure change cycle; the tissue is an artery moving during a heartbeat in the longitudinal direction, and the sensor is moved parallel to the longitudinal direction so that during at least one detection period the sensor has a fixed position relative to the wall of the artery; a position recording means coupled with the processor to record sensor positions; an actuator for controllably moving the sensor in the direction transverse to the measuring plane; the actuator has an adjustable speed of motion; a second activating means for activating the actuator; and the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat.

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Panescu et al disclose a means for visualizing internal structures and further disclose the signals are optical data detected with an optical sensor; the signals at as assumed cyclic pressure change are received at predetermined time intervals in a pressure change cycle; the tissue is an artery moving during a heartbeat in the longitudinal direction, and the sensor is moved parallel to the longitudinal direction so that during at least one detection period the sensor has a fixed position relative to the wall of the artery; a position recording means coupled with the processor to record sensor positions; an actuator for controllably moving the sensor in the direction transverse to the measuring plane; the actuator has an adjustable speed of motion; a second activating means for activating the actuator; and the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat. See Column 3, lines 59-67; Column 4, lines 1-5; Column 6, lines 61-65; Column 10, lines 44-67; Column 11, lines 1-12, 25-35 and 56-63; and Column 17, lines 21-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Torp et al and Porat et al to include the ability to control the movement of the sensors, as per the teachings of Panescu et al, since it would provide a means of accurately measuring a tissue parameter along a length of tissue.

19. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) and Porat et al (2003/0220556 A1) as applied to claims 1

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and 13 above, and further in view of Johnson et al (The Probability Density of Spectral Estimates..., 1999).

Torp et al and Porat et al, as discussed above, disclose a means of determining the tissue hardness, but fail to disclose an optimum overlap is determined by means of a probability function representing similarity between consecutive signals.

Johnson et al disclose the analysis of the statistics of spectral estimates using Welch's technique for spectrum estimation, and further disclose formulae that can be used to determine the optimum overlap of consecutive signals. See whole document.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Torp et al and Porat et al to include the ability to determine the optimum overlap of consecutive data, as per the teachings of Johnson et al, since it would provide a means of ensuring sufficient overlap of the incoming data to accurately determine the tissue type.

Response to Arguments

20. Applicant's arguments filed September 8, 2009 have been fully considered but they are not persuasive.

The Applicants argue the objection to the oath/declaration is in error. Specifically, the Applicants argue the oath/declaration was accepted when filed in 2004, and the citation of 37 CFR 1.52(c) is in error due to 37 CFR 1.52(c) discussing changes to the specification. The Examiner respectfully disagrees. At the time of filing, the oath/declaration was reviewed to ensure the oath/declaration has been submitted and

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meets the initial requirements set forth in the MPEP. The Examiner also has a duty to ensure the oath/declaration meets the requirements as set forth in the MPEP. 37 CFR 1.52(c)(1) specifically states: "Any interlineation, erasure, cancellation <u>or other</u> <u>alteration of the application papers filed must be made before the signing of any accompanying oath or declaration pursuant to § 1.63 referring to those application papers and should be dated and initialed or signed by the applicant on the same sheet <u>of paper.</u>" {emphasis added} Per 37 CFR 1.52, "application papers" include the oath/declaration and the specification (see 37 CFR 1.52(b)). The Applicant changed their mailing address, residence and citizenship information without initialing and dating the changes. Therefore the current oath/declaration is defective per the requirement of 37 CFR 1.52(c).</u>

The Applicants also state the claimed invention is not limited to any particular probability density function to determine the optimum overlap. Probability functions include but are not limited to: Binomial, Multinomial, Hypergeometric, Geometric, Pascal, Negative Binomial, Poisson, Normal, Gamma, Exponential, Beta, Uniform, Lognormal, Rayleigh, Cauchy, Chi-square, Weibull, Extreme value, t distributions, Triangular, F-density, and Students t-density. Based on the current specification, one of ordinary skill in the art would not be able to calculate the optimum overlap without knowing what probability functions can and cannot be used to calculate the optimum overlap. Therefore, the current specification fails to enable Claims 25 and 26.

As stated above, Claims 25 and 26, in conjunction with their respective independent claims, are indefinite. One of ordinary skill in the art, when reading the

claims, would not be able to determine what the determination of the optimum overlap would have to do with the means for generating tissue hardness. There is no correlation within the claims with respect to how an optimum overlap is being used to determine the tissue hardness.

The Applicants then argue the prior art rejection of Torp et al and Porat et al. In particular the Applicants argue Torp et al fail to disclose the claimed strain measurement to determine hardness or elasticity of tissue, but instead measure strain velocity (rate of change in strain). The Examiner respectfully disagrees. Torp et al does disclose the measurement of the strain velocity (rate of change in strain) of tissue. However, one of ordinary skill in the art would be able to determine that one would have to first measure the strain in order to determine any rate of change in strain. Furthermore, as stated in Column 9, lines 6-9 in Torp et al, "The strain velocity imaging described in this patent can be used to image the compressibility of the vessel wall. This can potentially be very important in the differentiation between various types of soft and hard plagues." Based on the above disclosure, one of ordinary skill in the art can readily ascertain the strain velocity measurements are used to determine the compressibility (elasticity) of tissue, and determine the type of plague by determining the hardness of the plague. Therefore Torp et al does provide the teaching for the measurement of the strain of the tissue and correlating the strain to either hardness or elasticity, as currently claimed.

The Applicants then argue Porat et al fail to disclose the sensor is moved during the receiving signals step in a direction transverse to the measuring plane and while the

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tissue is being subject to a varying pressure, as currently claimed in Claim 1. The Examiner respectfully disagrees. Porat et al discloses in Paragraph 286, moving a catheter with a plurality of measuring tips, said measuring tips are placed transversely to the longitudinal axis of the catheter, through a blood vessel. Since the sensor tips are oriented transversely to the longitudinal axis of the catheter, any movement within a blood vessel would result in moving the sensor in a direction transverse to the measuring plane. The Applicants further argue Porat et al fail to disclose "the tissue is subject of varying pressure". As defined in the current specification, "varying pressure" is defined as the result of a heart beat. Porat et al, as well as Torp et al, are directed towards diagnostic determinations of tissue types. One of ordinary skill in the art would be able to determine that both Porat et al and Torp et al teach the placement of a catheter within a blood vessel to determine the tissue type. One of ordinary skill in the art would further be able to determine such a diagnosis would obviously take place by measuring tissue parameters from a living person and not a cadaver. Therefore Porat et al (and Torp et al) teach the measurement while tissue is subject to varying pressure.

Regarding Claim 13, the Applicants argue Torp et al fail to disclose the measurement of strain and relating the strain measurement to elasticity or hardness parameter of the tissue. The Examiner respectfully disagrees. See above response with regards to Applicants' arguments. The Applicants further argue Torp et al also fail to disclose a display for displaying elasticity and/or hardness parameters of the tissue. Figure 1 of Torp et al, discloses a display (7). Furthermore, one of ordinary skill in the art would know any ultrasonic imaging system for performing diagnostic measurements

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requires a display. The Applicants then argue Porat et al fail to disclose the sensor's direction of movement, and the sensor is moved in a direction transverse to the measurement plane of the sensor. Again, the Examiner respectfully requests the Applicants to see the above response regarding the Applicants' arguments to Claim 1. The Applicants further argue Porat et al fail to disclose sensors movable through a blood vessel. Paragraph 0286, in Porat et al, clearly states device 200 (with sensing tips 101) moves within a blood vessel.

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Regarding Claim 12, the Applicants argue Panescu et al fail to disclose the tissue is an artery moving during a heartbeat in the longitudinal direction, such that the sensor has a fixed position relative to the wall of the artery. The Examiner respectfully disagrees. Figure 6 of Panescu et al shows an ultrasonic imaging embodiment wherein the catheter is placed within the intravascular system of a patient. The intravascular system includes arteries. Furthermore, one of ordinary skill in the art would know that arteries pulsate in reaction to a heart beat, such that the pulsation moves the blood through the system in a longitudinal direction. See Encyclopedia Britannica article regarding arteries as evidence. The splines 22 of the device anchor the catheter during the heartbeat cycle, such that the catheter would be in a fixed position relative to the wall of the artery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/ Examiner, Art Unit 3736